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EXAMINER

SINGH, SATYENDRA K

ART UNIT

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

Applicant's submission filed on 06/09/2009 has been entered.

Claims 1-21, 26-29, 34 and 35 have been previously canceled.

Claim 37 has been newly added by this amendment.

Claims **22-25, 30-33, 36 and 37** (applicant's elected invention of Group III, as currently amended), as currently amended, are examined on their merits in this office action.

Specification- Claim Objections

Claim 22 is objected to for minor informalities: claim recite the biological name of bacteria *Helicobacter pylori* in abbreviated form. Applicants are requested to use the **full name** as it appears for the first time in the claims. Appropriate correction is required.

The following contains new grounds of rejection necessitated by applicant's current amendments to claims.

Claim Rejections – 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claim 37 (newly presented; depends from claim 22) recites the limitation "**the capsule**" and "**the stomach wall**" in line 2 of the claim. There is insufficient antecedent basis for this limitation in the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

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such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names **joint inventors**. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims **22-25, 30-33, 36 and 37** (as currently amended) are/remain rejected under 35

U.S.C. 103(a) as being unpatentable over Marshall (US 6,228,605 B1; IDS) in view of Iddan et al (US 5,604,531; IDS) and Ishiyama et al (2002; [U]).

Claims are directed to a method for *in vivo* detection of *Helicobacter pylori* the method comprising: inserting an autonomous *in vivo* sensing device into an upper gastrointestinal tract of a patient, said device comprising a pH-sensitive color-changing material placed an optical window of the device, and a magnetic element disposed within said device; moving the autonomous *in vivo* device to contact at least one location of the upper gastrointestinal tract by an external magnetic field which moves said magnetic element; sensing pH at the location of the upper gastrointestinal tract using said pH-sensitive color-changing material; processing pH data sensed to determine presence of *H. pylori*; and transmitting pH data to an external receiving unit. (see specific recitations of claims 23-25, 30-33, 36 and 37)

Marshall (IDS) discloses a method for *in vivo* detection of *H. pylori* comprising inserting an autonomous *in vivo* sensing device (an endoscope; see abstract, figure 1, and summary of the invention, columns 3-6, in particular) into an upper gastrointestinal tract; sensing pH in at least

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one location in the upper gastrointestinal tract using said endoscope; and transmitting pH data visually through said endoscope to an external receiving unit (the viewer, for example); wherein the method further comprising indicating a pH value which is about equal to or exceeds a predetermined threshold; wherein sensing pH is by imaging (i.e. visual determination taken as imaging) a color changing pH indicator; the method according to claim 23, wherein the pH value is about 5.5 (see use of pH indicators such as bromothymol blue and phenol red; column columns 3-6, in particular). The method further comprising visually imaging the gastrointestinal tract using said endoscope, wherein the step of transmitting pH data further comprises transmitting image data (i.e. visual inspection/transmission through an endoscope); the method further comprising ingesting urea prior to inserting the endoscope (see column 6, 3rd paragraph, in particular); the method further comprising the step of causing the endoscope to contact at least one location of a stomach mucus by positioning a patient to achieve substantial covering of the patient's stomach (see *in vivo* detection of *H. pylori* using an endoscope, urea and pH indicators, as explicitly disclosed by Marshall on columns 3-6, and claims, in particular).

However, the method, wherein the device is an “**autonomous *in vivo* sensing device**”, said device comprising a pH-sensitive color-changing material placed on an optical window of the device, and a **magnetic element** disposed within said device; **moving** the autonomous *in vivo* device to contact at least one location of the upper gastrointestinal tract by **an external magnetic field** which moves said magnetic element; and wherein the transmitting is done **by radio frequency**, is not explicitly disclosed by the invention of Marshall.

Iddan et al (IDS) disclose an **autonomous video endoscope** that includes a swallowable capsule (including a camera system, an optical system and window for viewing and imaging an area of interest, such as upper GI tract; see column 3, in particular), a transmitter and a reception system, wherein the transmitter transmits the video output of the camera system and the reception system receives the transmitted video output using **radio frequency** (see Iddan et al,

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abstract, figure 1, 3B, and 5; column 1 and 3; and summary of the invention, in particular). In addition, Iddan et al clearly suggest that “*the capsule can traditionally include sensor elements for measuring pH, temperature, pressure, etc. These sensor elements are described in the prior art*”(see Iddan et al, column 3, lines 38-41, in particular, and column 3 in general).

Ishiyama et al [U] disclose use of magnetic materials (i.e. magnetic elements or magnetic micromachines, made of materials such as NdFeB magnet) that can be moved using an external magnetic field and can be applied in combination with various devices that are useful in biomedical applications such as catheters, etc. In addition, Ishiyama et al clearly suggest the use of said magnetic elements that can work without the use of wire (i.e. autonomously; see abstract, introduction, and summary, figures 1 and 9, in particular). Thus, use and benefits of magnetic elements that can be incorporated in wireless medical devices and can be moved, inside the body cavities, using an external magnetic field has been fully disclosed and contemplated by Ishiyama et al.

Thus, given the detailed disclosure for a method for *in vivo* detection of *H. pylori* in a patient or subject as disclosed by Marshall, at the time this invention was made, it would have been obvious for a person of ordinary skill in the art to modify the method of Marshall by 1) replacing or substituting the endoscope (i.e. the device) used by Marshall with a better device (i.e. a better functional analogue) disclosed by Iddan et al that works autonomously (by incorporating suitable CCD camera and optical systems having viewing window) using radio frequency to receive and transmit image signal as explicitly disclosed by the invention of Iddan et al (see Iddan et al, column 1, in particular); and 2) by incorporating a magnetic element (as explicitly taught by Ishiyama et al above) in the capsule or device such that it can be moved in

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the upper GI tract using an external magnetic field for sensing the change in pH at the intended site.

A person of ordinary skill in the clinical art would have been motivated to upgrade the method of Marshall as 1) Iddan et al disclose the potential benefits (i.e. the flexibility to move in the body cavities by its own weight, option of imaging the entire digestive tract and hard to reach parts without discomfort associated with older endoscopes; see Iddan et al, column 1, Background of the Invention, in particular) of using such independent devices that can be contained in a capsule, and that have all the required components to provide the capability of sensing internal pH, viewing and acquiring pH data using the color change of the pH indicators in the form of an image data, and storing and transmitting said data using RF signals, wherein the data can be further correlated with the presence and/or absence of the microbe, *H. pylori* as explicitly disclosed by Marshall's invention; and 2) Ishiyama et al clearly suggest the benefits of magnetic elements that can be incorporated in wireless medical devices to provide mobility and maneuverability inside the body cavity (such as upper GI tract) or body fluids, using an external magnetic field.

Therefore, such beneficial modifications would have been clearly within the perception of an artisan of ordinary skill in the clinical art at the time this invention was made, and the artisan would have had a reasonable expectation of success when modifying the method of Marshall, and using such autonomous device (in place of older endoscopes that could not function independently or wirelessly) as Iddan et al clearly provide use for such an autonomous video endoscope (see figure 6, and summary of the Invention, in particular); and as Ishiyama et al clearly demonstrate the use and benefits of magnetic elements (in the form of magnetic

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micromachines) that can be incorporated in medical devices and can be moved and operated/controlled using an external magnetic field without any need of wired systems (i.e. wirelessly and remotely). Since, the benefits accrued by incorporating such modifications in the method of Marshall would have been fully contemplated by an artisan of ordinary skill in the medical art at the time this invention was made, in view of the combined teachings of Iddan et al and Ishiyama et al, the invention as claimed fails to distinguish itself over the cited prior art references of record, and is therefore, considered obvious.

Given the detailed disclosure of Iddan et al for the autonomous device used for sensing pH, temperature, pressure, etc. (see Iddan et al, column 3, in particular), the limitations of claim 22, wherein the pH-sensitive color-changing material is **placed on the optical window of the device**, would have been clearly obvious to a person of ordinary skill in the art at the time this invention was made. Iddan et al provide detailed disclosures for the autonomous system that has viewing window, optical system, light source, mirror, CCD camera, etc. that are needed to detect and image the color change using the viewing window of said device, and transmit such signals using radio frequency to an external receiving unit. Thus, given the combined disclosure of Marshall for color changing materials (see Marshall, abstract, in particular, and discussion above) and the autonomous device having an optical window (see Iddan et al) that can wirelessly image and transmit signals to indicate any change in color at the desired location in the upper GI tract such as stomach, such adjustments (for example, placement of pH-sensitive color-changing material on the device's optical window) would have been a common sense approach to a method fully contemplated by an artisan of ordinary skill in order to image the material in question (i.e. in order to detect the changes in color of the pH-sensitive materials in view of

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Iddan's teachings for the autonomous imaging device), and therefore, it would have been obvious to place the color-changing material where it is in full view of the imager (i.e. on the optical window) as this is well known in the art of endoscopic procedures.

The limitations of newly added claim 37, wherein "*the step of moving comprises moving the capsule in a continuous track along the stomach wall*", would have been obvious to a person of ordinary skill in the art at the time this invention was made because the combine teachings of Marshall taken with Iddan et al and Ishiyama et al clearly disclose the fact that using an external magnetic field, an artisan in the clinical art can move the ingested capsule (having a magnetic element within) in the upper GI tract (including the stomach wall) of the patient as desired such that it provides a continuous track along the stomach wall in order to get the pH data in the form of a color change obtained through the optical window of the autonomous imaging device as disclosed by Iddan et al, and thereby determining the presence of *H. pylori*. Therefore, the invention as claimed, does not distinguish itself over the combined teachings of the cited prior art references of record.

Thus, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill in the clinical art at the time the claimed invention was made.

As per MPEP 2144.06, In order to rely on equivalence as a rationale supporting an obviousness rejection, the equivalency must be recognized in the prior art, and cannot be based on applicant's disclosure or the mere fact that the components at issue are functional or mechanical equivalents. In re Ruff, 256 F.2d 590, 118 USPQ 340 (CCPA 1958).

As per MPEP 2111.01, during examination, the claims must be interpreted as broadly as their terms reasonably allow. In re American Academy of Science Tech Center, F.3d, 2004 WL 1067528 (Fed. Cir. May 13, 2004)(The USPTO uses a different standard for construing claims than that used by district courts; during examination the USPTO must give claims their broadest reasonable interpretation.). This means that the words of the claim must be given their plain meaning unless applicant has provided a clear definition in the specification. In re Zletz, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989).

Response to Arguments-103(a) rejection

Applicant's arguments filed 06/09/2009 (as they pertain to the prior art rejection of record over claims 22-25, 30-33, 36 and 37) have been fully considered but they are not persuasive for the following reasons of record:

Applicants argue the following (see remarks, page 5):

"Applicants note that independent claim 22 recites that the autonomous in vivo sensing device comprises a pH-sensitive color-changing material placed on an optical window of the device and the step of "sensing pH at the location of the upper gastrointestinal tract using said pH-sensitive color-changing material". The Examiner states that this "would have been a common sense approach" and it would have been obvious to place the color changing material on the optical window. Applicants dispute the characterization by the Examiner of this feature being obvious. Indeed, as the instant application and Iddan et al. are commonly owned by the assignee of the instant application, Applicants are very familiar with the disclosure of Iddan et al. and are comfortable asserting that sensing pH at the location of the upper gastrointestinal tract using pH-sensitive color-changing material placed on an optical window of the device was not contemplated by Iddan et al. and is not obvious based upon the disclosure of Iddan et al. Applicants respectfully request that the Examiner withdraw his reliance on Iddan et al. for this feature and provide a reference for this specific structure as contemplated by the claims."

It is noted that the claims are directed to a process for detection of *H. pylori* bacteria (see claim 22, in particular) in the upper GI tract using an autonomous device that can sense pH data of color change and transmit said data for the determination of the presence of said bacteria, and which (i.e. the device) has been fully disclosed by the prior art reference of Iddan et al as discussed in detail in the rejection above. Iddan et al clearly suggest the fact that their "capsule can additionally include sensor elements for measuring pH, temperature, pressure, etc. ...described in the prior art" (see column 3, lines 38-41, in particular), and since the device operates by using a CCD camera and an optical unit having an observation window, an artisan of ordinary skill in the art would place or attach the color indicator or pH-sensitive color changing material on the optical window in order to image the pertinent data, i.e. the change in color of the indicator used. Such arrangements are taken to be within the ordinary skill in the clinical art, and

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are not deemed to patentably distinguish the instant method as claimed by applicants from the combined teachings of the cited prior art as relied upon in the 103(a) rejection of record.

Applicants further argue the following (see remarks, page 5):

"In addition, Applicants note that independent claim 22 recites the step of "moving the autonomous in vivo device to contact at least one location of the upper gastrointestinal tract by an external magnetic field which moves said magnetic element". Applicants contend that this step requires that the capsule be moved intentionally to contact at least one location of the upper gastrointestinal tract, e.g., the stomach wall. While Ishiyama et al. refers to moving an in vivo device by an external magnetic field which moves a magnetic element, Ishiyama et al. do not specifically teach that the capsule must intentionally contact at least one location of the upper GI tract. The claim step is quite different from the capsule possibly (or even probably, but possibly not) coming into contact with the stomach wall during its travels through the stomach."

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Moreover, the teachings of Ishiyama et al clearly provide the reason why an artisan of ordinary skill in the clinical art would combine a magnetic element that can assist in moving the capsule or the autonomous device of Iddan et al inside the upper GI tract at a desired location using an external magnetic field, which can be done wirelessly and remotely. Given such disclosure in the cited prior art, at the time the claimed invention was made, an artisan of ordinary skill in the clinical art would have been clearly motivated to modify the method of Marshall with the teachings of Iddan et al and Ishiyama et al in order to detect the presence of *H. pylori* in the upper GI tract of a patient using a modified autonomous device having a magnetic element that can be "intentionally" moved (see teachings of Ishiyama et al for moving the magnetic micromachines, and their applications for medical purposes), using an external magnetic field, to contact the desired locations in the upper GI tract, including stomach wall of the patient, with a reasonable expectation of success.

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Thus, applicant's arguments (see remarks, page 6, 2nd paragraph, in particular) that "...none of Marshall, Iddan or the Ishiyama et al. article discloses or suggests sensing pH at the location of the upper GI tract using a pH-sensitive color-changing material on the optical window of the in vivo device. In addition, none of Marshall, Iddan or the Ishiyama et al. article discloses or suggests moving the in vivo device to contact at least one location of the upper gastrointestinal tract by an external magnetic field which moves said magnetic element. Accordingly, amended independent claim 22 is not obvious over Marshall in view of Iddan and the Ishiyama et al. article", are fully considered, but are not found to be persuasive for the above discussed reasons of record.

The obviousness rejection of record over the combined teachings of the cited prior art is therefore properly made and maintained.

Nonstatutory Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims **22-25, 30-33, 36 and 37 are/remain** provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 18-23 of copending Application No. 10/524,553 (common inventor, same assignee). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims in said co-pending application are also directed to a similar subject matter as follows:

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"A method for *in vivo* analysis, the method comprising the steps of: obtaining a sample from a body lumen; combining *in vivo* the sample with agglutinative particles such that the combined sample and agglutinative particles gather into agglutination groups; and detecting at least one optical change in the combined sample and agglutinative particles"

Since, the disclosure of co-pending application specifically states that "*the agglutinated particles may include cells, such as bacteria (e.g. H. pylori)*" (see co-pending application, page 4, paragraph [0034], in particular), the two sets of claims are co-extensive in scope, and therefore, a obviousness-type double patenting rejection is required.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to ODP Arguments

Regarding the ODP rejection record, since applicants have deferred a response at the present time till an allowable subject matter is identified through prosecution (see remarks, page 6, last paragraph), and since, no terminal disclaimer or a pertinent argument has been filed, the rejection of record is deemed to be proper and is therefore, maintained.

Conclusion

NO claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SATYENDRA K. SINGH whose telephone number is (571)272-8790. The examiner can normally be reached on 9-5MF.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Satyendra K. Singh/
Examiner, Art Unit 1657

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